REMARKS

I. CLAIM STATUS

Claims 33-35, 38-44, 47-53, 56-59 and 61-63 stand rejected.

Claims 33-35, 38-44, 47-53, 56-59 and 61-81 are pending.

II. SPECIFICATION AMENDMENTS

The applicant respectfully amends the specification to delete the added paragraph that the examiner had considered new matter and amending a paragraph directly as stated in original claim 11 and 32. On page 9 twenty new paragraphs that are identical in wording and content to the originally filed claims 1-32. As Examiner is aware that the contents of claims, abstract and any drawings present at the time of filing may be amended into the body of the specification without creating any new matter issues. (See Bocciarelli v. Huffman, 232 F.2d 647, 109 USPQ 385, 388 (C.C.P.A. 1956)) Therefore this additional amendment to the specification contains ***no new matter*** because the claims were present at the time of filing.

III. CLAIM AMENDMENTS

Claims 33, 42, 51 and 61 have been amended to more particularly point out what the applicant considers their invention. No new matter was

introduced in the claim amendments. New claims 64-81 have been added. The newly added claims are fully supported throughout the specification, the claims containing means plus function language is defined by the teachings in the specification and therefore fully supported for all that is taught.

IV. REJECTION UNDER 35 U.S.C. 112(1)

Claims 33-35, 38-44, 47-53, 56-59 and 61-63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification . . . to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Independent claims 33, 42, 51 and 61 have been amended to clarify the ranges that are now clearly contained in the specification.

The Examiner's argument that the there is "but at most only such concentrations for specific compositions" is both factually and legally incorrect reasoning (See ***In re Smythe***, 480 F.2d 1376, 178 USPQ 279, 285 (C.C.P.A. 1973) discussing inherently disclosing) . As *Bocciarelli v. Huffman* states and is well founded in patent law the originally filed claims can be amended into the specification and are not treated as new matter because they were disclosed at the time of filing the application. All of the original 32 claims have been added as exactly worded in the original filing and therefore there is no new matter issues involved with the latest specification amendment.

The examiner's attention is directed toward the teachings of the originally filed specification on page 6 which states the following:

> While **L-arginine hydrochloride is the preferred active agent** because it is the agent in nature itself, it is non-toxic, is highly soluble and it is inexpensive, **other agents can be used which are also precursors or donors of nitric oxide**. **These include** D,L-arginine, **L-arginine**, alkyl(ethyl, methyl, propyl, isopropyl, butyl, isobutyl, t-butyl) esters of L-arginine and salts thereof. ***Pharmaceutically acceptable salts include hydrochloride, glutamate***, butyrate, and glycolate.
>
> **In the case of an alternative active agent were used it would b simply substituted for L-arginine** in a delivery preparation and the preparation used as in the case of the L-arginine preparation. (Emphasis added)

As clearly taught by the specification a "simple substitution" of one form of L-arginine can be switched for another. Original claims 9, 11, 20, 31 and 32 teach the use of L-arginine hydrochloride and L-arginine glutamate having a concentration of (0.25-25%) by weight of the preparation. The contents of all original claims have been amended into the specification. As clearly and unambiguously taught by the specification one form of L-arginine can be directly substituted with another. Therefore the teaching in the specification that a concentration of L-arginine hydrochloride is (0.25-25%) is applicable to all claims.

The bottom of page 9 of the original specification describes the teaching of the examples involving the scope of the invention:

Although the description above contains many specificities, **these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention**. Various other embodiments an ramifications are possible within this scope. Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than the examples given. (Emphasis added)

The examiner is aware under well accepted patent law that a dependent claim includes all limitations of the claims from which they depend. The examiner makes a factually incorrect assertion that "[*w*]*hile these ranges are disclosed for specific compositions, they are not broadly disclosed.*" The previously entered amendment that was a copy of the original claims allowed entry by the examiner are contrary to that assertion. An example of the broader teaching of originally filed claim 21 and dependent claim 31 is displayed below, which has been added in an amendment to now be part of the specification.

The amended specification and original claim 21 teaches:

> A method for promoting hair growth in a mammal comprising administering to the mammal **an effective dose of a nitric oxide precursor in a delivery vehicle**. (Emphasis added)

The specification and original claim 31 dependent on original claim 21 is as follows:

Where the cream consists of water (20-80%), mineral oil (3-18%), glyceryl stearate SE (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol (0.05- 5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), **L-arginine hydrochloride (0.25% to 25%),** sodium chloride (0.025% to 25%), magnesium chloride (0.25% to 25%) and choline chloride (0.25-25%). (Emphasis added)

The specification and original claim 32 dependent on original claim 31 and original claim 21 is as follows:

> **Wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%).** (Emphasis added)

The teachings provided by original claim 21 is clear on its face that what is claimed is an "effective dose of nitric oxide precursor in a delivery vehicle" to "promote hair growth". Claim 32 that depends upon claim 21 clearly and unambiguously modifies *"effective dose of nitric oxide precursor in a delivery vehicle"* with *"wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%)"*. The teaching of the invention in the specification, as now amended, to one skilled in the art is summarized as follows that L-arginine is a nitric oxide precursor, nitric oxide increases blood flow treating selected disorders, L-arginine is a nitric oxide precursor, one form of L-arginine can be "simply substituted" for another, "**an ffective d se f a nitric oxid pr curs r in a**

delivery vehicle. . . Wherein th nitric xide precurs r is L-arginine glutamate (0.25-25%)", and the specification states that the examples are just preferred embodiments of a larger invention and should not be limited to those examples.

The court has addressed the examiner's contention of enablement when only "specific embodiments" are disclosed in the specification instead of a broad description as the examiner incorrectly asserts is required. The court held that the specification and the claims may not be rejected as nonenabling under Section 112, first paragraph, when details of the claims are not directly disclosed in the specification are within the level of ordinary skill in the art. The specification need not recite details of the claims where one skilled in the art would consider these details obvious. (See *In re Skrivan*, 427 F.2d 801, 166 USPQ 85, 88 (C.C.P.A.)) The applicant has provided a roadmap above for L-arginine concentrations, as now contained in the specification, which is enabling for one minimally skilled in the art, not just skilled in the art. Page 6 of the specification has been amended to make it clear to one skilled in the art that the range of (0.25-25%) is applicable to all forms of L-arginine. The contention that the range "only discloses such concentration for specific combination" is not correct because it is enabled for all that it would reasonably teach to one skilled in the art without undue experimentation. The amendment of the specification fully and unambiguously supports

concentrations of the ionic salts of sodium chloride (0.025% to 25%), magnesium chloride (0.25% to 25%) and choline chloride (0.25-25%) for any purpose or combination in the claims, and to one reasonably skilled in the art it supports the concentration for potassium and lithium ionic salts.

Independent claims 33, 42, and 51 have been amended to remove the ranges for L-arginine and the ionic salts that were incorrectly rejected for lacking support in the specification. The rejection of claims 33-35, 38-44, 47-53 and 56-59 under 35 U.S.C. 112(1) are moot in light of the amendment of the claims. The aforementioned amended claims are allowable as now amended over the prior art as discussed in earlier responses and addressed by Mr. Fossel's declaration. The examiner has agreed with that reasoning and has properly removed all prior art rejections. With respect to the amended claims, the prior art fails to teach either singly or in combination to one skilled in the art motivation to one provide "**an effective concentration**" of L-arginine or L-arginine derivatives created when **used in combination with** a hostile biophysical environment to sufficiently transfer L-arginine into the skin to provide beneficial effects. The specification clearly defines "agent" and what is required to provide a hostile biophysical environment. The applicant respectfully request removal of the rejection of claims 33-35, 38-44, 47-53, 56-59 and 61-63 and allowance of the claims.

Newly added claims 64-81 are in full compliance with the requirements under 35 U.S.C. 112(1) with the amendment of the specification and claims. Claims 64, 66, 70, 72, 74, 76, 78 and 80 contain ranges for L-arginine and L-arginine derivatives and ionic salt that are fully supported by the specification. Allowance of newly added claims 64-81 is respectfully requested as they are not taught by the prior art.

CONCLUSION

The applicant respectfully requests allowance of all claims, because the claims are not taught by the cited art either singly or in combination and are in compliance with Section 112, first paragraph. Feel free to call collect with any questions regarding this submission

Dated March 14, 2003

Respectfully submitted,

LORUSSO LOUD & KELLY LLP

LORUSSO LOUD & KELLY LLP
440 Commercial Street
Boston, MA 02109
P{hone: (617) 227-0070
Fax.: (617) 723-4609

Jeffrey D. Washville
Reg. No. 46,366

Certification Under 37 CFR § 1.8

I hereby certify that this Response is being deposited with the United States Postal Service on 14 MAR 2003, in an envelope addressed to : Box Amendment, Commissioner for Patents, Washington, D.C. 20231.

Jeffrey D. Washville

MARKED UP SPECIFICATION

In the case of an alternative active agent were used it would be simply substituted for L-arginine in a delivery preparation and the preparation used as in the case of the L-arginine preparation. Wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%).

[As displayed in the examples above an effective concentration of a nitric oxide releasing substance selected from a member of the group consisting of L-arginine, L-arginine salts and L-arginine derivatives is (0.25% to 25%), when used in combination of salts each having a concentration of (0.25% to 25%). In the case of creating a high ionic strength ions such as but not limited to sodium chloride, potassium chloride, choline chloride, magnesium chloride, lithium chloride, alone or in combination were added in high concentration.]

A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a nitric oxide precursor. The nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine a salt, a complex or derivative thereof. Further comprising a

sufficient amount of ionic salt such as to create an ionic environment to cause absorption of the nitric oxide precursor.

A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a nitric oxide precursor. The nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine a salt, a complex or derivative thereof. The delivery vehicle is a hydrophobic penetrating cream containing little or no water.

A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a nitric oxide precursor. The nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine a salt, a complex or derivative thereof. Where the nitric oxide precursor is within a liposome ore liposome like structure. Further comprising a sufficient amount of ionic slat such as to create an ionic strength environment within the liposome to cause tissue absorption of the nitric oxide precursor.

A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a

nitric oxide precursor. The nitric oxide precursor is administered from a trans-dermal patch and wherein the nitric oxide precursor is L-arginine, a salt, a complex thereof. The trans-dermal patch further comprises a sufficient amount of ionic salts such as to create an ionic strength environment to cause tissue absorption of the L-arginine species.

A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a nitric oxide precursor. Where the cream consists of water (20-80%), mineral oil (3-18%), glyceryl stearate (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol (0.05- 5%), tocopherol acetate (0.5-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.025% to 25%), and magnesium chloride (0.25% to 25%). The cream further comprises choline chloride (0.25-25%). The nitric oxide precursor is L-arginine glutamate (0.25-25%).

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial

relaxing factor, nitric oxide. The delivery vehicle is a penetrating cream, a liquid, a lotion, and ointment or other topical preparation containing L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. The delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation containing L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide an extra force to cause tissue absorption of the L-arginine species.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. The delivery is a penetrating cream of hydrophobic nature containing oils, waxes and other hydrophobic materials and little water sufficient to aid in the absorption of the nitric oxide precursor L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial

relaxing factor, nitric oxide. The delivery vehicle is a penetrating cream, a liquid, a lotion, and ointment or other topical preparation containing L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. The delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation containing liposomes in which are encapsulated L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide extra force to cause tissue absorption of the L-arginine species.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. The delivery vehicle is contained in a condom or its equivalent which contains a penetrating cream, lotion, gel, ointment or other topical preparation containing L-arginine, a salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. The delivery vehicle is contained in a condom or

its equivalent which contains a penetrating cream, lotion, gel, ointment or other topical preparation containing L-arginine, a salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide an extra force to cause tissue absorption of the L-arginine species.

A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide. Where the delivery vehicle is a cream containing of water (20-80%), mineral oil (3-18%), glyceryl stearate (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate (0.1-11%), wheat germ oil (0.1-6%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), polysorbate 60 (0.1-5%), propylene glycol (0.05- 5%), vitamin E (0.02-4%), hyraluronic acid/collagen (0.05-5%), vitamin A&D (0.02%-4%), sorbitan stearate (0.05-5%), triethanolamine (0.01-4%), imidazolidinyl urea (0.01-4%), methylparaben (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), aloe vera extract (0.01-4%), L-arginine hydrochloride (0.25% to 25%), and sodium chloride (0.025% to 25%), choline chloride (0.25-25%), and magnesium chloride (0.25% to 25%).

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. The mammal is a female and lacking sufficient hair.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. The mammal is a male and lacking sufficient hair.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. Where the nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine, a salt, a complex or a derivative thereof. Further comprising a sufficient amount of ionic salt such as to create an ionic environment to cause absorption of the nitric oxide precursor.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. Where the nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine, a salt, a complex or a derivative thereof. Where the delivery vehicle is a hydrophobic penetrating cream containing little or no water.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. Where the nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine, a salt, a complex or a derivative thereof. Where the nitric oxide precursor is within a liposome or liposome like structure. Further comprising a sufficient amount of ionic salt such as to create an ionic strength environment to cause tissue absorption of the nitric oxide precursor.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. The nitric oxide precursor is administered from a trans-dermal patch and wherein the nitric oxide precursor is L-arginine, a salt, a complex thereof. The trans-dermal patch further comprises a sufficient amount of ionic slats such as to create an ionic strength environment to cause absorption of the L-arginine species.

A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle. Where the cream consists of water (20-80%), mineral oil (3-18%), glyceryl stearate SE (0.5-12%), squalene (0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), wheat germ oil (0.1-6%), glyceryl

stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol (0.05- 5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02%-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.025% to 25%), magnesium chloride (0.25% to 25%) and choline chloride (0.25-25%). Wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%).

MARKED UP CLAIMS

33. (Fourth Amendment) A method of increasing localized bloodflow in tissues to increase growth rate and repair of cells by delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, to skin comprising the step of :

applying topically to the skin a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance of [at least 0.25 % to 25% by weight, and] to increase localized tissue bloodflow when combined with a concentration of an [ionic salt] agent sufficient to create a hostile biophysical environment [wherein the ionic salt is selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride and magnesium chloride and mixtures thereof] which causes the substance to migrate from the delivery vehicle to the skin where the substance is absorbed by tissue causing increased rate of repair of cells in the area surrounding the skin wherein the substance was applied [wherein the ionic salt is 0.25% to 25% by weight].

42. (Fourth Amendment) A method of treating impotence in a male comprising:

delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives to the penis by

topically applying to the penis a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance [of at least 0.25 % to 25% by weight, and] to increase penis bloodflow when combined with a concentration of [ionic salt selected from the group consisting of sodium chloride, choline chloride potassium chloride, lithium chloride and magnesium chloride and mixtures thereof] an agent sufficient to create a hostile biophysical environment which causes the substance to migrate from the vehicle to the penis where the substance is absorbed by tissue [wherein the ionic salt is 0.25% to 25% by weight].

51. (Fourth Amendment) A method of promoting hair growth comprising:

delivering a substance that is a nitric oxide precursor selected from a group consisting of L-arginine and L-arginine derivatives, wherein a selected area of the skin where hair growth is desired by topically applying to the selected area of skin where hair growth is desired a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance [of at least 0.25 % to 25% by weight, and] to increase localized tissue bloodflow when combined with a concentration of an agent [ionic salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride and magnesium chloride and mixtures thereof] sufficient to create a hostile biophysical environment which causes the

substance to migrate from the vehicle to the selected area of skin where the substance is absorbed by tissue [wherein the ionic salt is 0.25% to 25% by weight].

61. (Fourth Amendment) A method of delivering a substance that is a nitric oxide precursor selected from the group consisting of L-arginine and L-arginine derivatives, to skin comprising the step of topically applying to the skin a delivery vehicle for the substance, said delivery vehicle containing an effective amount of the substance of [at least] 0.25 % to 25% by weight within a packaging selected from the group consisting of a liposome, emulsion of collagen, or collagen peptides said packaging being at a concentration sufficient to create an hostile biophysical environment which causes the liposome to migrate from the delivery vehicle to the skin where the substance is released from the packaging and absorbed by tissue.

64. (NEW) A method of topically treating a medical condition comprising the steps of:

selecting a condition from the group consisting of baldness, poor localized blood flow, leg ulcers, superficial wounds, sexual dysfunction and erectile dysfunction;

selecting a nitric oxide precursor means;

selecting a means of delivering the substance to the skin; and,

applying topically to the skin having the selected condition, an effective amount of the nitric oxide precursor means, the nitric oxide precursor means being 0.25 % to 25% by weight of the means of delivering the substance to the skin.

65. (NEW) The method of topically treating a medical condition of claim 64 further comprising the step of:

selecting a means of producing a hostile biophysical environment which increases the migration of the nitric oxide precursor means into the skin.

66. (NEW) The method of topically treating a medical condition of claim 65 wherein the means of producing a hostile biophysical environment is an ionic salt having a concentration of 0.25 to 25% of the means of delivering the substance to the skin.

67. (NEW) The method of topically treating a medical condition of claim 66 wherein the nitric oxide precursor means is selected from the group consisting of D,L-arginine, L-arginine, alkyls of L-arginine, esters of L-arginine, and salts of L-arginine.

68. (NEW) The method of topically treating a medical condition of claim 67 wherein the alkyls of L-arginine are selected from the group consisting of ethyl, methyl, propyl, isopropyl, butyl, isobutyl, and t-butyl.

69. (NEW) The method of topically treating a medical condition of claim 67 wherein the salts of L-arginine are selected from the group consisting of hydrochloride, glutamate, butyrate, and glycolate.

70. (NEW) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 33 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

71. (NEW) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 33 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

72. (NEW) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 71 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

73. (NEW) The method of increasing localized bloodflow in tissues to increase growth and repair of cells of claim 33 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly hydrophobic environments, polylysine, polyglutamine, polyasparate, copolymers of charged amino acids, oleoresin, and capsicum.

74. (NEW) The method of treating impotence of claim 42 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

75. (NEW) The method of treating impotence of claim 42 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

76. (NEW) The method of treating impotence of claim 75 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

77. (NEW) The method of treating impotence of claim 42 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly hydrophobic environments, polylysine, polyglutamine, polyasparate, copolymers of charged amino acids, oleoresin, and capsicum.

78. (NEW) The method of promoting hair growth of claim 51 wherein an effective amount of the substance is 0.25 to 25% by weight of the delivery vehicle.

79. (NEW) The method of promoting hair growth of claim 51 wherein the agent is a salt selected from the group consisting of sodium chloride, choline chloride, potassium chloride, lithium chloride, magnesium chloride, L-arginine chloride, L-arginine gluamate, L-arginine butyrate, L-arginine glutamate and mixtures thereof.

80. (NEW) The method of promoting hair growth of claim 79 wherein the agent has a concentration of 0.25 to 25% by volume of the delivery vehicle.

81. (NEW) The method promoting hair growth of claim 51 wherein the agent is selected from a group consisting of a high ionic strength environment, neutralization of L-arginine's charge in a complex, inclusion in a liposome, high pH, low pH, pharmaceutically acceptable acids, pharmaceutically acceptable bases, highly hydrophobic environments, polylysine, polyglutamine, polyasparate, copolymers of charged amino acids, oleoresin, and capsicum.